Introduction to the Principles and Practice of Clinical Research (IPPCR)

October 15, 2013 – March 24, 2014

All sessions will meet on Monday and Tuesday evenings from 5:00 p.m. to approximately 6:30 p.m. (Eastern Standard Time) in the Lipsett Amphitheater.

Introduction	
Tuesday, October 21 Session 1	Welcome (30 minutes) John I. Gallin, M.D. Director NIH Clinical Center
Module I: Study Design and Statistics	
Monday, October 21 Session 2	**Unit 1:** Overview of Clinical Study Design (1.5 hours) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM **Chapter: 19**
Tuesday, October 22 Session 3	**Unit 2:** Design of Epidemiologic Studies (1.5 hours) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM **Chapter: 18**
Monday, October 28 Session 4	**Unit 3:** Efficient Clinical Studies (1.25 hours) John Powers, III, M.D. Senior Medical Scientist, NCI Frederick **Chapter:**
Tuesday, October 29 Session 5	**Unit 4:** Study Participant Selection (1 hours) Catherine Stoney, Ph.D. Program Director Prevention and Population Sciences Program, NHLBI **Chapter: 2, 13, 19, 26**
Monday, November 4 Session 6	**Unit 5:** Measures (1 hour) David Lukenbaugh, Ph.D. Biostatistician Experimental Therapeutics and Pathophysiology Branch, NIMH **Chapter: 25, 26**
Tuesday, November 5 Session 7	**Unit 6:** Secondary Data/Meta Analysis (1.5 hours) Charles Natanson, M.D. Senior Investigator and Head Anesthesia Section Critical Care Medicine Department, CC

	Chapter: 27
Thursday, November 7 Session 8	Breakout Session (1 hour) Title – TBD Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM
Monday, November 11	FEDERAL HOLIDAY
Tuesday, November 12 Session 9	**Unit 7:** Issues in Randomization (1.5 hours) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM **Chapter: 20, 24**
Monday, November 18 Session 10	**Unit 8:** Overview of Hypothesis Testing (1.5 hours) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM **Chapter: 21, 24**
Tuesday, November 19 Session 11	**Unit 9:** Sample Size and Power (1.5 hours) Laura Lee Johnson, Ph.D. , Statistician Office of Clinical and Regulatory Affairs, NCCAM **Chapter: 22, 24**
Thursday, November 21 Session 12	Breakout Session (1 hour) Title – TBD Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM
Monday, November 25	RECESS
Tuesday, November 26 Session 13	History of Clinical Research: A Merging of Diverse Cultures (1 hour) John I. Gallin, M.D. Director NIH Clinical Center **Chapter: 1**
Monday, December 2 Session14	**Unit 10**: Designing and Testing Questionnaires (45 minutes) Gordon Willis, Ph.D. Cognitive Psychologist Applied Research Program, NCI

	Chapter: **Unit 11:** Quality of Life (45 minutes) John Ware, Ph.D. Chief Science Officer John Ware Research Group, Inc. **Chapter: 25**
Tuesday, December 3 Session 15	**Unit 12:** Conceptual Approach to Survival Analysis (1.5 hours) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM **Chapter: 23, 24**
Thursday, December 5 Session 16	Breakout Session – (1 hour) Title – TBD Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM
Monday, December 9 Session 17	**Unit 13:** Using Large Datasets for Population-Based Health Research (1 hour) Leighton Chan, M.D. Chief, Rehabilitation Medicine Department, CC **Chapter: 28**
Tuesday, December 10 Session 18	**Unit 14:** Summary (1.5 hours) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM **Chapter:**
Module II: Ethical, Legal, and Regulatory Considerations	
Monday, December 16 Session 19	**Unit 1:** Ethical Principles in Clinical Research (45 minutes) Christine Grady, R.N., Ph.D. Head, Section on Human Subjects Research Chief, Bioethics Department, CC **Chapter: 2**
	Unit 2: Research with Vulnerable Participants (45 minutes) David Wendler, Ph.D. Head, Unit on Vulnerable Populations Section on Human Subjects Research, Bioethics Department, CC **Chapter: 2, 5**
Tuesday, December 17 Session 20	**Unit 3:** Inclusion of Women and Minorities in Clinical Trials (1 hour) Miriam Kelty, Ph.D. Special Volunteer Former Associate Director, Extramural Activities, NIA

	Chapter: 13 **Unit 4:** Clinical Research from the Patient's Perspective (30 minutes) Jerry Sachs, B.A. Manager Guest Services (Retired) Smithsonian Museum of Natural History **Chapter: 17**
Monday, December 23	RECESS
Tuesday, December 24	RECESS
Monday, December 30	RECESS
Tuesday, December 31	RECESS
Monday, January 6 Session 21	**Unit 5**: Legal Issues in Clinical Research (1 hour) Carrie Pottker-Fishel, J.D. Attorney Advisor Office of General Counsel, NIH **Chapter: 11**
Tuesday, January 7 Session 22	**Unit 6:** FDA Product Regulation (1.5 hours) Robert Yetter, Ph.D. Associate Director for Review Management Center for Biologics Evaluation Research, FDA **Chapter: 7**
Monday, January 13 Session 23	**Unit 7:** Institutional Review Boards (1 hour) Jerry Menikoff, M.D., J.D. Director, Office for Human Research Protections Office of Public Health and Science, DHHS **Chapter: 5, 6**
Tuesday, January 14 Session 24	**Breakout Session:** Mock IRB (2 hours) Jerry Menikoff, M.D., J.D. Director, Office for Human Research Protections Office of Public Health and Science, DHHS **Chapter: 5, 6**
Module III: Preparing and Monitoring Clinical Studies	
Monday, January 20	FEDERAL HOLIDAY
Tuesday, January 21 Session 25	**Unit 1:** Information Resources for Clinical Research (1.5 hours) Josh Duberman, M.L.I.S. Informationist/Research Librarian, NIH Library **Chapter:**
Monday, January 27 Session26	**Unit 2:** Protocol Development (1 hour) Wendy Weber, N.D., Ph.D., M.P.H.

	Program Officer Division of Extramural Research, NCCAM **Chapter: 29, 32** **Unit 3:** Protocol Mechanics and Tools (30 minutes) Philip Lightfoot, B.S., B.A. Systems Analysis Department of Clinical Research Informatics, CC **Chapter: 32**
Tuesday, January 28 Session 27	**Unit 4:** Development of Manuals of Operating Procedures (1.5 hours) Wendy Weber, N.D., Ph.D., M.P.H. Program Director Division of Extramural Research, NCCAM **Chapter: 29**
Monday, February 3 Session 28	**Unit 5:** Pharmaceutical Development: Management of Projects (1 hour) Christopher Breder, M.D., Ph.D. Medical Officer Center for Drug Evaluation and Research, FDA **Chapter: 7, 26, 37, 43**
Tuesday, February 4 Session 29	**Unit 6:** Evaluation of a Protocol Budget (1.5 hours) Phyllis Klein, R.N., CCRC, BSN Director, Regulatory Support and Compliance Washington University in St. Louis **Chapter: 33**
Monday, February 10 Session 30	**Unit 7:** NIH Peer Review Process (1 hour) Valerie Prenger, Ph.D., M.H.S. Director Office of Scientific Review, NHLBI **Chapter: 36**
Tuesday, February 11 Session 31	**Unit 8:** Design of Case Report Forms (1 hour) Diane St. Germain, R.N., M.S., C.R.N.P. Nurse Consultant Division of Cancer Prevention, NCI **Chapter: 33, 37**
Monday, February 17	FEDERAL HOLIDAY
Tuesday, February 18 Session 32	**Unit 9:** Data Management in Clinical Trials (1 hour) Diane St. Germain, R.N., M.S., C.R.N.P. Nurse Consultant Division of Cancer Prevention, NCI **Chapter: 8**
Monday, February 24 Session 33	**Unit 10:** Basic Data Representation (TBD) (1 hour) Jim Cimino, M.D. Chief

	Laboratory for Informatics Development, CC **Chapter:**
Tuesday, February 25 Session 34	**Unit 11:** Data & Non-Data Aspects of Quality Control in Clinical Studies (1 hour) Elizabeth Ness, R.N., MSN Staff Development NCI/CCR **Chapter:**
Monday, March 3 Session 35	**Unit 12:** Data and Safety Monitoring Committees (1 hour) Pamela Shaw, Ph.D. Assistant Professor Department of Biostatistics and Epidemiology Perelman School of Medicine University of Pennsylvania **Chapter: 9**
Tuesday, March 4 Session 36	**Unit 13:** Clinical Trial Registration and Results Reporting (1 hour) Deborah Zarin, M.D. Assistant Director for Clinical Research Projects Lister Hill National Medical Center for Biomedical Communications, NIH **Chapter: 15**
Module IV: Miscellaneous Topics	
Monday, March 10 Session 37	**Unit 1:** Technology Transfer (1.5 hours) Bruce Goldstein, J.D. Unit Coordinator Technology Transfer Branch, NCI **Chapter: 30, 31**
Tuesday, March 11 Session 38	**Unit 2:** Scientific Conduct (1 hour) James L. Gulley, M.D., Ph.D., F.A.C.P. Director Clinical Trials Group, Center for Cancer Research, NCI **Chapter: 4, 12**
Monday, March 17 Session 39	**Unit 3:** The Clinical Researcher and the Media (45 minutes) John Burklow, M.S. Associate Director for Communications Office of Communications and Public Liaison, NIH **Chapter: 16**
Tuesday, March 18 Session 40	**Unit 4:** Health Disparities Research (1 hour) Irene Dankwa-Mullan, M.D., M.P. H. Acting Director

	Office of Innovation and Program Coordination, NIMHD **Chapter: 46**
Monday, March 24 Session 41	**Unit 5:** Dissemination and Implementation Research (1 hour) Catherine Stoney, Ph.D. Program Director Prevention and Population Sciences Program, NHLBI **Chapter:** **Unit 6:** Community-Based Participatory Research (30 minutes) Francisco Sy, M.D., Dr PH Director Division of Extramural Activities and Science Programs, NIMHD **Chapter: 46**